IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE
AT NASHVILLE

GREGORY L. MOODY, *Plaintiff*, v. C.R. BARD, INC. and BARD PERIPHERAL VASCULAR, INC., *Defendants*.	)	Cause No. _____ COMPLAINT FOR DAMAGES DEMAND FOR A JURY TRIAL

COMPLAINT FOR DAMAGES AND DEMAND FOR JURY TRIAL

Plaintiff GREGORY L. MOODY, by and through his undersigned attorneys, hereby sue Defendants C.R. BARD, INC.; BARD PERIPHERAL VASCULAR, INC., a subsidiary corporation and/or division of C.R. BARD, INC., (collectively, the "Defendants") and allege as follows:

1. This is an action for damages relating to Defendants' development, testing, assembling, manufacture, packaging, labeling, preparing, distribution, marketing, supplying, and/or selling the defective product sold under the name "inferior vena cava filter" (hereinafter "IVC filter")

I. THE PARTIES

2. Plaintiff, Gregory L. Moody ("Plaintiff") is a citizen of and resident in Goodlettsville, Tennessee, which is located in Davidson County, Tennessee.

3. The Bard G2 Filter System which gives rise to this cause of action was implanted into Mr. Moody's body at MidHudson Regional Hospital located in Poughkeepsie, New York.

4. Venue is proper in this judicial district as a substantial part of the events or omissions giving rise to the claim occurred within this judicial district and the Defendants regularly conduct business in this District.

5. Defendant C.R. Bard, Inc. ("Bard") is a corporation duly organized and existing under the laws of the state of Delaware with its principal place in New Jersey. C.R. Bard may be served through its registered agent for service of process, CT CORPORATION SYSTEM, 3800 N CENTRAL AVE SUITE 460, PHOENIX, AZ 85012. Bard at all times relevant to this action, designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed, distributed, and sold the G2 Filter System to be implanted in patients throughout the United States, including Tennessee. At all times relevant hereto, Defendant Bard was or has been engaged in business in Tennessee, and has conducted substantial business activity in Tennessee. Defendant has also carried on solicitations or service activities in the State of Tennessee.

6. Defendant Bard Peripheral Vascular, Inc. ("BPV") is a wholly owned subsidiary corporation of defendant Bard, with its principal place of business at 1625 West 3rd Street, Tempe, Arizona and may be served through its registered agent for service of process, CT CORPORATION SYSTEM, 3800 N CENTRAL AVE SUITE 460 , PHOENIX, AZ 85012. BPV at all times relevant to this action, designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed, distributed, and sold the G2 Filter System to be implanted in patients throughout the United States, including Tennessee. At all times relevant hereto, Defendant BPV was or has been engaged in business in Tennessee, and has conducted substantial business activity in Tennessee. Defendant has also carried on solicitations or service activities in the State of Tennessee.

II. JURISDICTION AND VENUE

7. Jurisdiction is proper in this Court under 28 U.S.C. § 1332(a)(1) because the plaintiff and the defendants are citizens of different states, and the amount in controversy exceeds $75,000, excluding interest and costs.

8. Venue is proper in this Court under 28 U.S.C. § 1391, as a substantial part of the events or omissions giving rise to the claim occurred within this judicial district and the Defendants regularly conduct business in this District.

III. GENERAL FACTUAL ALLEGATIONS

9. Plaintiff brings this case for serious injuries he suffered as a result of a surgically implanted medical device, known as a G2 Filter System (hereafter G2, G2 Filter, or G2 Filter System), fragmenting resulting in migration of the filter causing perforation of the Vena Cava, serious illness, and ongoing physical, emotional, and economic damages.

10. The G2 Filter was designed, manufactured, prepared, compounded, assembled, processed, labeled, marketed, distributed, and sold by Defendants from approximately January 2011 to the present for prevention of blood clots (thrombi) from traveling from the lower portions of the body to the heart and lungs.

11. At all times relevant to this action and prior to Plaintiff Gregory L. Moody being implanted with a G2 Filter, Defendants misrepresented the safety of the G2 Filter and negligently designed, manufactured, prepared, compounded, assembled, processed, labeled, marketed, distributed and sold the G2 Filter as a safe and effective device to be surgically implanted to prevent blood clots from travelling from the lower portions of the body to the heart and lungs.

12. At all times relevant to this action and prior to Plaintiff Gregory L. Moody being implanted with a G2 Filter, Defendants knew and had reason to know that the G2 Filter was not

safe for the patients for whom they were prescribed and implanted because once implanted the devices were prone to fracturing, migrating, excessively tilting, perforation the inferior vena cava wall and otherwise malfunctioning.

13. At all times relevant to this action and prior to Plaintiff Gregory L. Moody being implanted with a G2 Filter, the Defendants knew and had reason to know that patient implanted with a G2 Filter had an increased risk of suffering life threatening injuries, including but not limited to: death; hemorrhage; cardiac/pericardial tamponade; cardiac arrhythmia and other symptoms similar to myocardial infarction; severe and persistent pain; perforations of tissue, vessels, and organs; and inability to remove the device.

14. At all times relevant to this action and prior to Plaintiff Gregory L. Moody being implanted with a G2 Filter, the Defendants and had reason to know the G2 Filters contained conditions, which Defendants did not intend, which resulted in the devices not performing as safely as the ordinary customer would expect.

15. Despite having knowledge of the dangers presented by the G2 Filter, the Defendants failed to adequately warn Plaintiff's health care providers and/or the public at large of these dangers.

INFERIOR VENA CAVA FILTERS GENERALLY

16. Inferior Vena Cava (IVC) Filters first came on the medical market in the 1960's. Over the years, several different medical device manufacturers have introduced several different designs of IVC filters.

17. An IVC filter is a device that is designed to filter or "catch" blood clots (called "thrombi") that travel from the lower portions of the body to the heart and lungs. IVC filters may

be designed to be implanted, either permanently or temporarily, in the human body, more specifically, within the inferior vena cava.

18. The inferior vena cava is a vein that returns blood to the heart from the lower portions of the body. In certain people, for various reasons, thrombi travel from the vessels in the legs and pelvis, through the vena cava and into the lungs. Oftentimes, these thrombi develop in the deep leg veins. These thrombi are called "deep vein thrombosis" or "DVT". Once thrombi reach the lungs, they are considered "pulmonary emboli" or "PE".

19. Certain people are at increased risk for the development of DVT or PE. For instance, someone who undergoes knee or hip joint replacement is at risk for developing DVT/PE. Obese patients are also at increased risk for DVT/PE. So too are people who have vascular diseases or whom have experienced previous strokes. A number of other conditions predispose people to develop DVT/PE.

20. Those people at risk for DVT/PE can undergo medical treatment to manage the risk. For example, a doctor may prescribe medications like Heparin, Warfarin, or Lovenox to regulate the clotting factor of the blood. In some people who are at high risk for DVT/PE, or who cannot manage their conditions with medications, physicians may recommend surgically implanting an IVC filter to prevent thromboembolic events.

21. As stated in this Complaint, IVC filters have been on the market for decades. The first IVC filters were permanent filters. These devices were designed to be left in a patients IVC permanently and have long term follow-up data (of up to 20 years and longer) supporting their use and efficacy. Beginning in 2003, manufactures also began marketing what are known as optional or retrievable filters. These filters are designed so that they can be surgically removed from a patient after the risk of PE has passed. These IVC filter designs, however, were not intended to

remain within the human body for indeterminate periods of time. In other words, the initial designs of retrievable IVC filters were intended to remain implanted for a finite period of time. The recovery Filter, the G2, G2 Express, Eclipse and Meridian Filter manufactured by Bard and BPV are examples of retrievable filters.

THE RECOVERY FILTER

22. In 2002, Bard and BPV submitted a notification of intent to the FDA to market the "Recovery® Filter System" (hereafter "Recovery" or "Recovery Filter") for the prevention of recurrent pulmonary embolism by placement in the inferior vena cava.[1] On November 27, 2002, the FDA cleared the Recovery Filter for marketing and use in the prevention of recurrent pulmonary embolism via *permanent* placement in the vena cava in the following situations:

a. Pulmonary thromboembolism when anticoagulants are contraindicated;
b. Failure of anticoagulant therapy for thromboembolic disease;
c. Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced;
d. Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated.

23. In April 2003, Bard and BPV submitted a Section 510(k) premarket notification of intent to market the Recovery® Filter for the additional intended use of *optional retrieval*. The FDA cleared this additional intended use on July 25, 2003.

[1] Bard and BPV submitted the notification under Section 510(k) of the United States Food, Drug and Cosmetic Act ("Act") of 1976 (21 U.S.C. 321 *et seq*). The 510(k) review process requires any entity engaged in the design, manufacture, distribution or marketing of a device intended for human use to notify the FDA 90 days before it intends to market the device and to establish that the device is substantially equivalent to a legally marketed predicate device. (21 C.F.R. §§ 807.81, 807.92(a)(3)). Substantial equivalence means that the new device has the same intended use and technological characteristics as the predicate device. This approval process allows a manufacturer to bypass the rigorous safety scrutiny required by the pre-market approval process.

24. Bard and BPV began actually marketing the device in April 2003, but did not begin full market release until 2004. Bard and BPV were aware that the Recovery filter was also used extensively off-label, including for purely prophylactic reasons for trauma patients or patients with upcoming surgeries such as bariatric procedures.

25. The Recovery Filter consists of two (2) levels of six (6) radially distributed NITINOL struts that are designed to anchor the filter into the inferior vena cava and to catch any embolizing clots. There are six short struts, which are commonly referred to as the arms, and six long struts, which are commonly referred to as the legs. Each strut is held together by a single connection to a cap located at the top of the device. According to the Patent filed for this device, the short struts are primarily for "centering" or "positioning" with the vena cava, and the long struts with attached hooks are designed primarily to prevent the device from migrating in response to "normal respiratory movement" or "pulmonary embolism."

26. As noted above, the Recovery Filter is constructed with NITINOL, which is an acronym that stands for Nickel Titanium Naval Ordnance Laboratory. NITINOL possesses "shape memory." Meaning, NITINOL will change shape according to changes in temperature, and then, retake its prior shape after returning to its initial temperature. When placed in saline, therefore, the NITINOL struts become soft and can be straightened to allow delivery through a small diameter catheter. The metal struts then reassume their original shape when warmed to body temperature in the vena cava.

27. The Recovery filter is inserted by a catheter that is guided by a physician (normally an interventional radiologist) through a blood vessel into the inferior vena cava. The Recovery Filter is designed to be retrieved in a similar fashion. The implanting physician normally reviews an imaging study prior to placement to determine size of IVC, renal vein location, and to identify

any venous anomalies or clots in the vena cava. Following placement, the physician will normally use an imaging study to confirm successful placement.

28. The Recovery Filter is prone to an unreasonably high risk of failure and patient injury following placement in the human body. Multiple studies have reported Bard's Recovery Filter to have a fracture and migration rate ranging from 21% to 31.7%.[2] When such failures occur, shards of the device or the entire device can travel to the heart, where it can cause cardiac tamponade, perforation of the atrial wall, myocardial infarction and death. These fractured shards may also become too embedded in tissue or migrate to locations, such as the lungs, such that they are too dangerous to remove. These patients are exposed to a lifetime of future risk.

29. The Recovery Filter similarly poses a high risk of tilting and perforating the vena cava walls. When such failures occur, the device can perforate the duodenum, small bowel, ureter, which may lead to retroperitoneal hematomas, small-bowel obstructions, extended periods of severe pain, and/or death. Further, given the risks of injury in attempting to remove devices that have perforated the vena cava, the device may be irremovable. These patients are faced with a lifetime of future risk.

30. The Recovery Filter failures described above occur at a substantially higher rate than with other IVC filters.

31. Soon after the Recovery Filter's introduction to the market, Bard and BPV began receiving large numbers of adverse event reports from health care providers.

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[2] *See e.g.,* Hull JE, Robertson SW. Bard Recovery Filter: evaluation and management of vena cava limb perforation, fracture, and migration. *J Vasc Interv Radiol.* 2009;20(1):52-60; Nicholson W, *et al.* Prevalence of Fracture and Fragment Embolization of the Bard Recovery and Bard G2 Cava Filters and Clinical Implications Including Cardiac Perforation and Tamponade. *Arch. Int. Med.* 2010 Nov.; 170:1827-31.

30. The adverse event reports (AERs) associated with IVC filter devices demonstrates that Bard's IVC Filters are far more prone to device failure then are other similar devices. A review of the FDA MAUDE database from the years 2004-2008 reveals data to establish that Bard's IVC filters are responsible for the following percentages of all AERs:

a. 50% of all adverse events

b. 64% of all occurrences of migration of the device

c. 69% of all occurrences of vena cava wall perforation

d. 70% of all occurrences of filter fracture.

31. These failures are attributable, in part, to the fact that the Recovery Filter was designed so as to be unable to withstand the normal anatomical and physiological loading cycles exerted *in vivo*.

32. In addition to design defects, the Recovery Filter suffers from manufacturing defects. These manufacturing defects include, but are not limited to, the existence of "draw markings" and circumferential grinding markings on the exterior of the surface of the device. The presence of these draw markings and/or circumferential grinding markings further compromises the structural integrity of the device while *in vivo*. In particular, the Recovery Filter is prone to fail at or near the location of draw markings/circumferential grinding markings on the struts of the device. Put simply, the Recovery Filter is not of sufficient strength to withstand normal placement within the human body. The presence of the aforementioned exterior manufacturing defects makes the device more susceptible to failure.

33. Bard and BPV knew that no clinical testing, such as animal studies or simulated use tests, was conducted to determine whether the Recovery Filter would perform safely once implanted in the human body and subjected normal *in vivo* stresses.

34. Soon after the Recovery Filter's introduction to the market in 2003, Bard and BPV began receiving large numbers of adverse event reports ("AERs") from health care providers reporting that the Recovery® Filter was fracturing post-implantation and that fractured pieces and/or the entire device were migrating throughout the human body, including to the heart and lungs. Bard and BPV also received large numbers of AERs reporting that the Recovery Filter was found to have excessively tilted and/or perforated the inferior vena cava post-implantation. These failures were often associated with reports of severe patient injuries such as:

a. Death;
b. Hemorrhage;
c. Cardiac/pericardial tamponade (pressure caused by a collection of blood in the area around the heart);
    i. Cardiac arrhythmia and other symptoms similar to myocardial infarction;
d. Severe and persistent pain; and
e. Perforations of tissue, vessels and organs.

35. Within the first year of full market release of the Recovery Filter, Bard and BPV received at least 32 AERs reporting that the Recovery Filter had fractured *in vivo* and at least 22 AERs reporting that the entire device had migrated *in vivo*. Of the 22 reported migration failures, at least nine (9) were reported to have been associated with patient death.

36. From 2003 through September 2005, Bard and BPV received ever growing numbers of AERs reporting the above described failures and patient injuries. Defendants knew or should have known that the failure rates associated with the Recovery Filter were substantially higher than other similar products on the market, yet Bard and BPV failed to warn consumers of this unreasonably dangerous device.

37. In late 2004 or early 2005 Bard and BPV, without notifying consumers of the design and manufacturing flaws inherent in the Recovery Filter, began redesigning the Recovery Filter in an attempt to correct those flaws. The redesigned filter is known as the G2 Filter, which stands

for second generation Recovery Filter. Bard later manufactured the G2 Express, G2x and the Eclipse filter, which are based on the Recovery Filter design. Once Bard and BPV had obtained FDA approval to market the redesigned product in or around August 2005, Bard and BPV quietly stopped marketing the Recovery Filter. Bard and BPV failed, however, to make any effort to notify consumers of the risk inherent in the use of the Recovery Filter.

THE G2, G2 EXPRESS AND G2x FILTER SYSTEM

38. In 2005, Bard and BPV redesigned its first generation retrievable filter, Recovery Filter, in an attempt to fix its design and manufacturing flaws. The redesigned filter is known as the G2 Filter, which stands for second generation Recovery Filter.

39. On August 10, 2005, Bard and BPV submitted a Section 510(k) premarket notification of intent to market the G2 Filter for the prevention of recurrent pulmonary embolism via permanent placement in the inferior vena cava. Bard and BPV cited the Recovery Filter as the substantially equivalent predicate device. Bard and BPV stated that the differences between the Recovery Filter and the G2 Filter were primarily dimensional and no material changes or additional components were added. On August 29, 2005, the FDA cleared the G2 Filter for the same intended uses as the Recovery Filter, except that it was not cleared for retrievable use.[3]

40. Even after the redesigned G2 Filter was cleared for use, Bard and BPV failed to take any steps to recall the Recovery Filter and/or to notify consumers that the failure rates associated with the Recovery Filter were substantially higher than other similar products on the market.

[3] The FDA did not clear the G2® Filter to be used as a retrievable filter until January 15, 2008.

41. Bard and BPV marketed the G2 Filter as having "enhanced fracture resistance," "improved centering," and "increased migration resistance." Despite these claims, however, Bard and BPV failed to ensure that the changes made to the G2 Filter were sufficient to cure the defective and unreasonably dangerous nature of the device. Thus, the G2 Filter shares the same defects and health risks as its predicate device.

42. The G2 Filter's design causes it to be of insufficient integrity and strength to withstand normal *in vivo* body stresses within the human body so as to resist fracturing, migrating, tilting, and/or perforating the inferior vena cava.

43. Also, like its predecessor, in addition to design defects, the G2 Filter suffers from manufacturing defects. These manufacturing defects include, but are not limited to, the existence of "draw markings" and circumferential grinding markings on the exterior of the surface of the device. The presence of these draw markings and/or circumferential grinding markings further compromises the structural integrity of the G2 Filter while *in vivo*. In particular, the G2 Filter is prone to fail at or near the location of draw markings/circumferential grinding markings on the struts of the device. Put simply, the G2 Filter is not of sufficient strength to withstand normal placement within the human body. The presence of the aforementioned exterior manufacturing defects makes the device more susceptible to fatigue failure.

44. As with the Recovery Filter, Bard and BPV immediately began receiving large numbers of AERs reporting that the G2 Filter was, *inter alia*, fracturing, migrating, excessively tilting, and perforating the vena cava once implanted. These failures were again often associated with reports of severe patient injuries such as:

a. death;
b. hemorrhage;
c. cardiac/pericardial tamponade (pressure caused by a collection of blood in the area around the heart);

d. cardiac arrhythmia and other symptoms similar to myocardial infarction;
e. severe and persistent pain;
f. and perforations of tissue, vessels and organs.

45. Defendants represent the fracture rate of the G2 Filter to be 1.2%. Based upon a review of the data available in the public domain (including the FDA MAUDE database statistics and the published medical literature), this representation does not accurately reflect the true incidence of device fracture for the G2 Filter.

46. A review of the MAUDE database from the years 2004-2008 reveals data to establish that the Bard and BPV's vena cava filters (including the G2 Filter) are responsible for the majority of all reported adverse events related to inferior vena cava filters.

47. The G2 Express filter was cleared by the FDA on July 30, 2008. The only significant difference between this filter and the G2 was a new snare tip which was designed in an effort to optimize retrieval. Bard launched and began marketing the G2 Express in August 2008. The G2 and the G2 Express are the same filter, from a design standpoint, and share the same defects and complications.

48. The G2x filter was cleared by the FDA on October 31, 2008. As with the G2 Express, the G2x had minimal design difference between it and the G2 Filter. Bard launched the G2x Filter in January 2009. The G2, G2 Express, and the G2x are the same filter, from a design standpoint, and share the same defects and complications.

49. Upon information and belief, Plaintiff alleges that as early as 2003, Bard and BPV were aware and had knowledge of the fact that the Recovery Filter was defective and unreasonably dangerous and was causing injury and death to patients who had received it. Similarly, Bard and BPV were aware as early as 2005 that the G2 Filter System family was defective and unreasonably dangerous and was causing injury and death to patients who had received it. And due to the

similarities in design, Bard should have known that the G2 Express and G2x were just as dangerous and defective.

50. Data establishes that the failure rate of the G2 Filter System, and filters within that family, was/is exceedingly higher than the rate that Bard and BPV have in the past, and currently continue to publish to the medical community, members of the public. Further, Bard and BPV are aware or should have been aware that the G2 Filter, the G2 Express, and the G2x have a substantially higher failure rate than other similar products on the market, yet they have failed to warn consumers of this fact.

51. Upon information and belief, from the time the G2 Filter System became available on the market, the Defendants Bard and BPV embarked on an aggressive campaign of "off label marketing" concerning the G2 Filter System. This included representations made to physicians, healthcare professionals, and other members of the medical community that the G2 Filter System was safe and effective for retrievable use prior to the FDA approving the G2 Filter System for retrievable use.

52. Despite having knowledge as early as 2005 of the unreasonably dangerous and defective nature of the product, Bard and BPV consciously disregarded the known risks and continued to actively market and offer for sale the G2 Filter System, the G2 Express, and the G2x.

THE ECLIPSE VENA CAVA FILTER

53. In an effort to resolve the complications associated with the G2 filter, the G2 Express, and the G2x, Bard designed the Eclipse Vena Cava Filter as the next generation in its filter family.

54. The Eclipse Filter was cleared by the FDA on January 14, 2010. The only design changes from the G2 family of filters to the Eclipse was that hooks were added to the legs of the

filter and the struts of the filter were electropolished. The Eclipse Filter continued to share several of the same design defects and complications associated with the Recovery Filter and G2 family of filters due to the fact that the Eclipse design was based on its predecessors.

55. Bard launched the Eclipse Filter in 2010. Soon thereafter, Bard began receiving similar complaints associated with the Eclipse filter as at it had with the predecessor filters. For the reason that the Eclipse is based on Bard's previous filter designs, the Eclipse filter shares the same or similar design and manufacturing defects as Bard's previous filters and suffers from the same complications and defects.

THE MERIDIAN FILTER

56. In August of 2011, the Meridian Filter was cleared by the F.D.A. for introduction to the global market. The Meridian Filter was also submitted under the notification provisions of section 510(k) of the United States Food, Drug and Cosmetic Act ("Act") of 1976 (21 U.S.C. 321 *et seq.*). The Defendants represented to the F.D.A. that the Meridian was substantially similar to the Eclipse Filter System (predicate device).

57. The Meridian Filter system was the next-generation of Bard's retrievable or optional filters. The Meridian Filter is made of the same nickel-titanium alloy, Nitinol, as the Bard Recovery, G2and Eclipse Filters. The design of the Meridian is based on the Eclipse Filter System which is based entirely off the G2 filter[4], which is also designed, manufactured and sold by the Defendants. Like the Eclipse, the Nitinol wires used in the Meridian Filter are electropolished prior to the forming of the filter.

[4] "G2 filter" – is meant to include the G2 as well as the G2 Express filters manufactured by Bard. The only difference between the G2 and the G2 Express is a hook at the top of the device for a physician to attempt removal.

58. As seen with the Recovery, G2 and Eclipse Filters, soon after its introduction to the market, reports were made that the Meridian Filters were fracturing, perforating, migrating, and/or tilting in the patients it which they were implanted. The Meridian Filter System was still plagued with manufacturing and design defects that were causing damage to the general public.

59. Upon information and belief, Plaintiff alleges that as early as 2011, Bard and BPV were aware and had knowledge of the fact that the Meridian Filter was defective and unreasonably dangerous and was causing injury to patients who had received it. Bard and BPV knew or should have known that the similarities in design between the Meridian Filter and its predecessors made the Meridian Filter just as dangerous and prone to defects and complications.

60. Data establishes that the failure rate of the Meridian Filter, and its predecessors, was/is exceedingly higher than the rate that Bard and BPV have in the past, and currently continue to publish to the medical community, members of the public. Further, Bard and BPV are aware or should have been aware that the Meridian Filter had a substantially higher failure rate than other similar products on the market, yet they have failed to warn consumers of this fact.

61. Upon information and belief, from the time the Meridian Filter became available on the market, the Defendants Bard and BPV embarked on an aggressive campaign of "off label marketing" concerning the Eclipse Filter. This included representations made to physicians, healthcare professionals, and other members of the medical community that the Meridian Filter was safe and effective for classes of patients when data and the Meridian Filter's own clearance did not allow for such representations.

62. Despite having knowledge as early as 2011, and even earlier based on predecessor filters, of the unreasonably dangerous and defective nature of the product, Bard and BPV

consciously disregarded the known risks and continued to actively market and offer for sale the Meridian Filter.

63. The conduct of Bard and BPV as alleged in this Complaint constitutes willful, wanton, gross, and outrageous corporate conduct that demonstrates a conscious disregard for the safety of Plaintiff and the community at large. Bard and BPV had actual knowledge of the dangers presented by the Meridian Filter, yet consciously failed to act reasonably to:

a. Inform or warn Plaintiff, his physicians, or the public at large of these dangers;
b. Establish and maintain an adequate quality and post-market surveillance system; and
c. Recall the Meridian Filter System from the market.

64. Plaintiff further alleges that Bard and BPV acted in willful, wanton, gross and total disregard for the health and safety of the users or consumers of their Meridian Filter, acted to serve their own interests, and having reason to know and consciously disregarding the substantial risk that their product might kill or significantly harm patients, or significantly injure the rights of others, consciously pursued a course of conduct knowing that such conduct created a substantial risk of significant harm to other persons.

65. The failures of the Meridian Filter are attributable, in part, to the fact that the Meridian Filter was designed so as to be unable to withstand the normal anatomical and physiological loading cycles exerted *in vivo.*

WHAT HAPPENS WHEN A MERDIAN FILTER SYSTEM FAILS

66. The failure (fracture and/or migration) of the Meridian Filter System leads to a number of different, and potentially fatal, complications. These complications include, but are not limited to:

a. Death;
b. Hemorrhage;

c. Cardiac/pericardial tamponade (pressure caused by a collection of blood in the area around the heart);
d. Severe and persistent pain; and
e. Perforation of tissue, vessels and organs.

67. The person who experiences failure (fracture and/or migration) of the Meridian Filter System typically experiences an acute onset of pain. This typically results in the person presenting to an emergency room, hospital, and/or physician for evaluation.

THE CASE FOR MEDICAL MONITORING

68. In certain cases, medical monitoring is required to evaluate whether a Meridian Filter System (or portions of the Meridian Filter) has fractured, tilted, perforated and/or migrated (collectively referred to herein as "device failure" or "failure"). In order to determine whether failure of the Meridian Filter System has occurred, imaging studies must be performed. Typically, these imaging studies will include un-enhanced computed tomography scan (CT Scan) so that the filter may be visualized. CT Scan imaging produces an image of the filter and is able to reveal whether the filter has fractured or migrated.

69. Patients requiring medical monitoring are recommended[5] to undergo regular and frequent imaging studies of the device or portions of the device at least once or twice annually. As long as the device, or portions of the device, remains within the body of the patient, the potential

[5] Research studies performed in 2008 call for the need of regular and frequent medical monitoring for a patient who had the Recovery™ vena cava filter implanted in their body. This 2008 research study performed by Jeffrey Hull, M.D. recommends regular and frequent monitoring of patients in whom the Recovery Filter System remains implanted. (*Retrieval of the Recovery Filter after Arm Perforation, Fracture, and Migration to the Right Ventricle*, Hull *et. al.*, J. Vasc. Intern. Radiol. 2008; 19:1107.1111). Dr. Hull specifically recommends "imaging with un-enhanced abdominal CT to look for arm perforation, fracture, or migration to further evaluate the scope and risk posed by this [the Recovery™] filter."

for future device failure exists. Consequently, these patients require regular and frequent medical monitoring for the duration of time the device, or portions of the device, remain within their bodies.

70. Patients eligible for medical monitoring of the Meridian Filter System or portions of the device need not have experienced past failure of the Meridian Filter System. For example, patients who have undergone implant of the Meridian Filter System frequently learn that the Meridian Filter cannot be removed due to the fact that it has "grown into" tissue, but, the fracture, tilt or migration of the device may not yet have occurred. Other patients, like Mr. Moody, may experience frature and migration of a piece of the filter to other organs, such as the heart, where the risk of removal currently weighs against removal. As a result of the inability to remove the Meridian Filter System, the device must remain permanently implanted in the patient, for the patient's lifetime. Although these patients may not yet have experienced device failure, they are at risk for future device failure and require regular and frequent monitoring to evaluate the integrity of the Meridian Filter System. In addition to the aforementioned imaging studies, endovascular intervention (typically cardiac catheterization) may also be used by medical professionals to diagnose or discover whether fractured portions of the Meridian Filter System have migrated to the heart or lungs. Furthermore, endovascular surgery may assess the nature and extent of the damage resulting from failure of the Meridian Filter System.

71. In those instances where device fracture has occurred, and depending on the circumstances particular to the patient, a person may be required to undergo one or all of the following medical procedures:

a. CT Scanning or other imaging studies;
b. Cardiac Catheterization;
c. Open heart surgery;
d. Removal of the G2 Filter System from the vena cava.

72. The G2 Filter System was placed in Plaintiff's body on or about January 1, 2011. On or about January 1, 2012, Plaintiff presented to the hospital for shortness of breath. Later that same year, 2014, the Plaintiff's physicians determined that, in light of the patient's current physical condition, no attempts would be taken to remove the filter. Plaintiff was caused to undergo medical treatment as a result of the failure of the Meridian Filter System. Plaintiff has incurred significant medical expenses and has endured extreme pain and suffering, loss of enjoyment of life, and other losses, some of which are permanent in nature. As a result of the failure of the G2 Filter System, Plaintiff has become impaired and his ability to earn wages has been diminished, and will remain so in the future. The defective Meridian Filter remained in Plaintiff's body.

73. As a direct and proximate result of the conduct and defective product of the Defendants C.R. Bard, Inc. and Bard Peripheral Vascular, Inc., as alleged in this Complaint, Plaintiff Gregory L. Moody has suffered permanent and continuing injury, loss of enjoyment of life, pain, suffering, and impairment. Plaintiff has suffered emotional trauma, harm and injuries. Plaintiff's ability to carry on the affairs of his daily life has been impacted and diminished, and will continue to diminish in the future.

74. As a direct and proximate result of the conduct and defective product of the Defendants, C.R. Bard, Inc. and Bard Peripheral Vascular, Inc., as alleged in this Complaint, the Plaintiff has incurred substantial medical expenses, and will continue to incur substantial medical expenses into the future.

THE NECESSITY FOR MEDICAL MONITORING

75. As a direct and proximate result of the conduct and defective product of the Defendants, C.R. Bard, Inc. and Bard Peripheral Vascular, Inc., as alleged in this Complaint, medical monitoring is necessary for Plaintiff Gregory L. Moody. Medical monitoring includes.

a. Regularly scheduled CT scans or other appropriate imaging studies; and/or
b. Potential cardiac catheterization or other endovascular procedure to detect the presence of migrated pieces of the G2 Filter System; and/or Physicians' visits and examinations.

THE DEFENDANTS' KNOWLEDGE OF THE FAILURE OF THE G2 FILTER SYSTEM AND THE DANGERS ASSOCIATED WITH THE DEVICE

76. Upon information and belief, Plaintiff alleges that as early as 2011, the Defendants C.R. Bard, Inc. and Bard Peripheral Vascular, Inc. were aware and had knowledge of the fact that the Meridian Filter System was defective and unreasonably dangerous and was causing serious and potentially life-threatening injuries to patients who had received the Meridian Filter System.

77. From the time the G2 Filter System became available on the market, the Defendants C.R. Bard, Inc. and Bard Peripheral Vascular, Inc., made representations to physicians, healthcare professionals, and other members of the medical community that the G2 Filter System was safe and effective for retrievable use, when they knew or should've known it wasn't.

78. The conduct of the Defendants C.R. Bard, Inc. and Bard Peripheral Vascular, Inc. as alleged in this Complaint, constituted, willful, wanton, gross, and outrageous corporate conduct that demonstrates a conscious disregard for the safety of the Plaintiff Gregory L. Moody. The Defendants C.R. Bard, Inc. and Bard Peripheral Vascular Inc. had actual knowledge of dangers to the life and limb of the Plaintiff Gregory L. Moody presented by the G2 Filter System, yet consciously failed to act reasonably to:

a. Inform or warn the Plaintiff, his physicians, or the public at large of the dangers; and
b. Recall the G2 Filter System from the market in a timely and safe fashion;

79. Despite having knowledge as early as 2011 of the unreasonably dangerous and defective nature of the product, the Defendants C.R. Bard, Inc. and Bard Peripheral Vascular, Inc. consciously disregarded the known risks and continued to actively market and offer for sale the

G2 Filter System. Plaintiff alleges that the Defendants acted in willful, wanton, gross manner, and in total disregard for the health and safety of the users or consumers of its G2 Filter System, including Plaintiff Gregory L. Moody, and acted to serve their own interests and having reason to know and consciously pursued a course of conduct knowing that such conduct created a substantial risk of significant harm to other persons. Therefore, Defendants should be required to respond to the Plaintiff in the form of a punitive or exemplary damage award.

THE FEDERAL REQUIREMENTS

80. Federal regulation states that "recall means a firm's removal or correction of a marketed product that the Food and Drug Administration considers to be in violation of the laws it administers and against which the agency would initiate legal action, e.g. seizure." See 21 CFR §7.3(g).

81. Federal regulation states that "recall classification means the numerical designation, i.e., I, II or III, assigned by the Food and Drug Administration to a particular product recall to indicate the relative degree of health hazard presented by the product being recalled." See 21 CFR §7.3(m).

82. Federal regulation states that "class II is a situation in which use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote." See 21 CFR §7.3(m).

83. The classification of the product withdrawals and corrections of the Defendant's devices (described above) as Class II Recalls by the F.D.A confirms by definition that the devices were in violation of federal law and that initiation of legal action or seizure would be indicated for these devices.

84. Pursuant to federal law, a device is deemed to be adulterated if, among other things, it fails to meet established performance standards, or if the methods, facilities or controls used for its manufacture, packing, storage or installation are not in conformity with federal requirements. See 21 U.S.C. §351.

85. Pursuant to federal law, a device is deemed to be misbranded if, among other things, its labeling is false or misleading in any particular manner, or if it is dangerous to health when used in the manner prescribed, recommended or suggested in the labeling thereof. See 21 U.S.C. §352.

86. Pursuant to federal law, manufacturers are required to comply with F.D.A. regulation of medical devices, including F.D.A. requirements for records and reports, in order to prohibit introduction of medical devices that are adulterated or misbranded, and to assure the safety and effectiveness of medical devices. In particular, manufacturers must keep records and make reports if any medical device that may have caused or contributed to death or serious injury, or if the device has malfunctioned in a manner likely to cause or contribute to death or serious injury. Federal law also mandates that the F.D.A. establish regulations requiring a manufacturer of a medical device to report promptly to F.D.A. any correction or removal of a device undertaken to reduce a risk to health posed by the device, or to remedy a violation of federal law by which a device may present a risk to health. See 21 U.S.C. §360(i).

87. Pursuant to federal law, the Secretary of Health and Human Services may prescribe regulations requiring that the methods used in, and that facilities and controls used for, the manufacture, pre-production design validation (including a process to assess the performance of a device but not including an evaluation of the safety or effectiveness of a device), packaging, storage, and installation of a device conform to current good manufacturing proactive, as

prescribed in such regulations, to assure that the device will be safe and effective and otherwise in compliance with federal law. See 21. U.S.C §360j(f).

88. Pursuant to F.D.A. regulation, adverse events associated with a medical device must be reported to F.D.A. within 30 days after the manufacturer becomes aware that a device may have caused or contributed to death or serious injury, or that a device has malfunctioned and would be likely to cause or contribute to death or serious injury if the malfunction was to recur. Such reports must contain all information reasonably known to the manufacturer, including any information that can be obtained by analysis, testing, or other evaluation of the device, and any information in the manufacturer's possession. In addition, manufacturers are responsible for conducting an investigation of each adverse event, and must evaluate the cause of the adverse event. See 21 CFR §803.50.

89. Pursuant to federal regulation, manufacturers of medical devices must also describe in every individual adverse event report whether remedial action was taken in regard to the adverse event, and whether the remedial action was reported to F.D.A. as a removal or correction of the device. See 21 CFR §803.52.

90. Pursuant to federal regulation, manufacturers must report to F.D.A. within five (5) business days after becoming aware of any reportable MDR event or events, including a trend analysis that necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health. See 21 CFR §803.53.

91. Pursuant to federal regulation, device manufacturers must report promptly to F.D.A. any device corrections and removals, and maintain records of device corrections and removals. F.D.A. regulations require submission of a written report within ten (10) working days of any correction or removal of a device initiated by the manufacturer to reduce a risk to health

posed by the device, or to remedy a violation of the Act caused by the device, which may present a risk to health. The written submission must contain, among other things, a description of the event giving rise to the information reported and the corrective or removal actions taken, and any illness or injuries that have occurred with use of the device, including reference to any device report numbers. Manufacturers must also indicate the total number of devices manufactured or distributed which are subject to the correction or removal, and provide a copy of all communications regarding the correction or removal. See 21 CFR §806.

92. Pursuant to federal regulation, manufacturers must comply with specific quality system requirements promulgated by F.D.A.. These regulations require manufacturers to meet design control requirements, including but not limited to conducting design validation to ensure that devices conform to defined user needs and intended uses. Manufacturers must also meet quality standards in manufacture and production. Manufacturers must establish and maintain procedures for implementing corrective actions and preventive actions, and investigate the cause of nonconforming products and take corrective action to prevent recurrence. Manufacturers are also required to review and evaluate all complaints and determine whether an investigation is necessary. Manufacturers are also required to use statistical techniques where necessary to evaluate product performance. See 21 CFR §820.

93. The regulations requiring conformance to good manufacturing practices are set forth in 21 CFR §820 et seq. As explained in the Federal Register, because the Current Good Manufacturing Practice (CGMP) regulations must apply to a variety of medical devices, the regulations do not prescribe the details for how a manufacturer must produce a device. Rather, the quality system regulations provide a framework of basic requirements for each manufacturer to use in establishing a quality system appropriate to the devices designed and manufactured, and the

manufacturing processes employed. Manufacturers must adopt current and effective methods and procedures for each device they design and manufacture to comply with and implement the basic requirements set forth in the quality system regulations.

94. Pursuant to 21 CFR §820.1(c), the failure to comply with any applicable provision in Part 820 renders a device adulterated under section 501(h) of the Federal Food Drug & Cosmetic Act ("the Act") (21 U.S.C. § 351).

95. Pursuant to 21 CFR §820.5, each manufacturer shall establish and maintain a quality system that is appropriate for the specific medical device designed or manufactured. "Quality system" means the organizations structure, responsibilities, procedures, processes, and resources for implementing quality management. See 21 CFR §820.3(v).

96. Pursuant to 21 CFR §820.22, each manufacturer shall establish procedures for quality audits and conduct such audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system.

97. Pursuant to 21 CFR §820.30(a), each manufacturer shall establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met.

98. Pursuant to 21 CFR §820.30(d), each manufacturer shall establish and maintain procedures for defining and documenting design output in terms that allow an adequate evaluation of conformance to design input requirements.

99. Pursuant to 21 CFR §820.30(e), each manufacturer shall establish and maintain procedures to ensure that formal documented reviews of the design results are planned and conducted at appropriate stages of the device's design development.

100. Pursuant to 21 CFR §820.30(f), each manufacturer shall establish and maintain procedures for verifying the device design to confirm that the device design output meets the design input requirements.

101. Pursuant to 21 CFR §820.30(g), each manufacturer shall establish and maintain procedures for validating the device design. Design validation shall be performed under defined operating conditions on initial production units, lots, or batches, or their equivalents. Design validations shall ensure that devices conform to defined user needs and intended uses and shall include testing of production units under actual or simulated use conditions.

102. Pursuant to 21 CFR §820.30(h), each manufacturer shall establish and maintain procedures to ensure that the device design is correctly translated into production specifications.

103. Pursuant to 21 CFR §820.30(i), each manufacturer shall establish and maintain procedures for the identification, documentation, validation or where appropriate verification, review, and approval of design changes before their implementation.

104. Pursuant to 21 CFR §820.70(a), each manufacturer shall develop, conduct, control, and monitor production processes to ensure that a device conforms to its specifications. Where deviations from device specifications could occur as a result of the manufacturing process, the manufacturer shall establish and maintain process control procedures that describe any process controls necessary to ensure conformance to specifications. Such process controls shall include:

a. Documented instructions, standard operating procedures (SOP's), and methods that define and control the manner of production;

b. Monitoring and control of process parameters and component and device characteristics during production;

c. Compliance with specified reference standards or codes;

d. The approval of processes and process equipment; and

e. Criteria for workmanship which shall be expressed in documented standards or by means of identified and approved representative sample.

105. Pursuant to 21 CFR §820.70(b), each manufacturer shall establish and maintain procedures for changes to a specification, method, process, or procedure.

106. Pursuant to 21 CFR §820.70(c), each manufacturer shall establish and maintain procedures to adequately control environmental conditions that could reasonably be expected to have an adverse effect on product quality, including periodic inspection of environmental control system(s) to verify that the system, including necessary equipment, is adequate and functioning properly.

107. Pursuant to 21 CFR §820.70(e), each manufacturer shall establish and maintain procedures to prevent contamination of equipment or product by substances that could reasonably be expected to have an adverse effect on product quality.

108. Pursuant to 21 CFR §820.70(g), each manufacturer shall ensure that all equipment used in the manufacturing process meets specified requirement and is appropriately designed, constructed, placed, and installed to facilitate maintenance, adjustment, cleaning and use.

109. Pursuant to 21 CFR §820.70(h), each manufacturer shall establish and maintain procedures for the use and removal of manufacturing material which could reasonably be expected to have an adverse effect on product quality to ensure that it is removed or limited to an amount that does not adversely affect the device's quality.

110. Pursuant to 21 CFR §820.70(i), when computers or automated data processing systems are used as part of production or the quality system, the manufacturer shall validate computer software for its intended use according to an established protocol.

111. Pursuant to 21 CFR §820.72, each manufacturer shall ensure that all inspection, measuring, and test equipment, including mechanical, automated, or electronic inspection and test

equipment, is suitable for its intended purposes and is capable of producing valid results. Each manufacturer shall establish and maintain procedures to ensure that equipment is routinely calibrated, inspected, checked, and maintained.

112. Pursuant to 21 CFR §820.75(a), where the results of a process cannot be fully verified by subsequent inspection and test, the process shall be validated with a high degree of assurance and approved according to established procedures. "Process validation" means establishing by objective evidence that a process consistently produces a result or product meeting its predetermined specifications. See 21 CFR §820.3(z)(1).

113. Pursuant to 21 CFR §820.75(b), each manufacturer shall establish and maintain procedures for monitoring and control of process parameters for validated processes to ensure that the specified requirements continue to be met. Each manufacturer shall ensure that validated processes are performed by qualified individuals.

114. Pursuant to 21 CFR §820.90, each manufacturer shall establish and maintain procedures to control product that does not conform to specified requirements.

115. Pursuant to 21 CFR §820.100, each manufacturer shall establish and maintain procedures for implementing corrective and preventive action. The procedures shall include requirements for:

a. Analyzing processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product, or other quality problem,

b. Investigating the cause of nonconformities relating to product, processes and the quality system;

c. Identifying the action(s) needed to correct and prevent recurrence of nonconforming product and other quality problems;

d. Verifying or validating the corrective and preventative action to ensure that such action is effective and does not adversely affect the finished device;

e. Implementing and recording changes in methods and procedures needed to correct and prevent identified quality problems;

f. Ensuring that information related to quality problems or nonconforming product is disseminated to those directly responsible for assuring the quality of such product or the prevention of such problems; and

g. Submitting relevant information on identified quality problems, as well as corrective and preventative actions, for management review.

DEFENDANTS' MERIDIAN FILTER SYSTEM IS A 510(k) CLEARED MEDICAL DEVICE

116. Defendants submitted a §510(k) premarket notification and obtained marketing clearance for its Meridian Filter System from the F.D.A. under Section 510(k) of the Act. *See* 21 U.S.C. §360 *et seq.*

117. Under the §510(k) approval process, the F.D.A. determined that Defendants' Meridian Filter System was "substantially equivalent" to devices that have been reclassified in accordance with the provisions of the Act and did not require F.D.A. approval of a pre-market approval application (PMA).

118. Upon information and belief, Defendants' Meridian Filter System is adulterated pursuant to 21 U.S.C. §351 because, among other things, it failed to meet established performance standards, and/or the methods, facilities, or controls used for its manufacture, packing, storage or installation are not in conformity with federal requirements. *See* 21 U.S.C. §351.

119. Upon information and belief, Defendants' Meridian Filter System is misbranded because, among other things, it is dangerous to health when used in the manner prescribed, recommended or suggested in the labeling thereof. *See* 21 U.S.C. §352.

120. Upon information and belief, Defendants' Meridian Filter System is adulterated

pursuant to 21 U.S.C. §351 because Defendants failed to establish and maintain CGMP for their Meridian Filter System in accordance with 21 CFR §820 *et seq.*, as set forth above.

121. Upon information and belief, Defendants failed to establish and maintain CGMP with respect to the quality audits, quality testing and process validation for their Meridian Filter System.

122. As a result of Defendants' failure to establish and maintain CGMP as set forth above, Defendants' Meridian Filter System was defective and failed, resulting in injuries to the Plaintiff.

123. If Defendants had complied with the federal requirements regarding CGMP, Defendants' Meridian Filter System would have been manufactured properly such that it would not have resulted in injuries to the Plaintiff.

SPECIFIC FACTUAL ALLEGATIONS AS TO PLAINTIFF

124. On or about January 1, 2011, Plaintiff underwent surgical placement of a G2 Filter System.

125. This G2 Filter was designed, manufactured, prepared, compounded, assembled, processed, marketed, distributed, and sold by Defendants Bard and BPV.

126. Plaintiff later discovered, through a CT examination, that the G2 filter had perforated through his vena cava wall.

127. As a result of the failure of the G2 Filter System, Plaintiff has become impaired and his ability to earn wages has been diminished, and will remain so in the future. The defective G2 Filter remains in Plaintiff's body.

FRUADULENT CONCEALMENT

128. Any applicable statutes of limitation have been tolled by the knowing and active concealment and denial of material facts known by Defendants when they had a duty to disclose those facts. They have kept Plaintiff ignorant of vital information essential to the pursuit of their claims, without any fault or lack of diligence on Plaintiff's part, for the purpose of obtaining delay on Plaintiff's part in filing on their causes of action. Defendants' fraudulent concealment did result in such delay.

129. Defendants are estopped from relying on the statute of limitations defense because Defendants failed to timely disclose, among other things, facts evidencing the defective and unreasonably dangerous nature of the Recovery®, G2®, Eclipse and Meridian Filter Systems.

130. The Defendants are and were under a continuing duty to disclose the true character, quality and nature of the device that was implanted in Plaintiff, but instead they concealed them. Defendants' conduct, as described in this complaint, amounts to conduct purposely committed, which Defendants must have realized was dangerous, heedless and reckless, without regard to the consequences or the rights and safety of Plaintiff.

CORPORATE/VICARIOUS LIABILITY

131. At all times herein mentioned, each of the Defendants was the agent, servant, partner, aider and abettor, co-conspirator and/or joint venturer of each of the other Defendants herein and was at all times operating and acting within the purpose and scope of said agency, service, employment, partnership, conspiracy and/or joint venture and rendered substantial assistance and encouragement to the other Defendants, knowing that their collective conduct constituted a breach of duty owed to the Plaintiff.

132. There exists and, at all times herein mentioned, there existed a unity of interest in ownership between certain Defendants and other certain Defendants such that any individuality

and separateness between the certain Defendants has ceased and these Defendants are the alter ego of the other certain Defendants and exerted control over those Defendants. Adherence to the fiction of the separate existence of these certain Defendants as entities distinct from other certain Defendants will permit an abuse of the corporate privilege and would sanction a fraud and/or would promote injustice.

133. At all times herein mentioned, Defendants, and each of them, were engaged in the business of, or were successors in interest to, entities engaged in the business of researching, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging, prescribing and/or advertising for sale, and selling products for use by the Plaintiff. As such, each Defendant is individually, as well as jointly and severally, liable to the Plaintiff for Plaintiff's damages.

134. At all times herein mentioned, the officers and/or directors of the Defendants named herein participated in, authorized and/or directed the production and promotion of the aforementioned products when they knew, or with the exercise of reasonable care and diligence should have known, of the hazards and dangerous propensities of said products, and thereby actively participated in the tortious conduct that resulted in the injuries suffered by the Plaintiff.

IV. CAUSES OF ACTION

COUNT ONE: NEGLIGENCE

135. Plaintiff re-alleges and incorporates by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

136. At all times relevant to this cause of action, the Defendants Bard and BPV were in the business of designing, developing, setting specifications, manufacturing, marketing, selling, and distributing the G2 Filter.

137. Defendants designed, manufactured, marketed, inspected, labeled, promoted, distributed and sold the G2 Filter that was implanted in Plaintiff.

138. Defendants had a duty to exercise reasonable and prudent care in the development, testing, design, manufacture, inspection, marketing, labeling, promotion, distribution and sale of the Meridian Filter so as to avoid exposing others to foreseeable and unreasonable risks of harm.

139. Defendants knew or reasonably should have known that the G2 Filter was dangerous or was likely to be dangerous when used in its intended or reasonably foreseeable manner.

140. At the time of manufacture and sale of the G2 Filter, Defendants knew or should have known that the G2 Filter:

a. Was designed and manufactured in such a manner so as to present an unreasonable risk of fracture of portions of the device;

b. Was designed and manufactured so as to present a unreasonable risk of migration of the device and/or portions of the device; and/or

c. Was designed and manufactured so as to present a unreasonable risk of the device tilting and/or perforating the vena cava wall; and/or

d. Was designed and manufactured to have unreasonable and insufficient strength or structural integrity to withstand normal placement within the human body.

141. At the time of manufacture and sale of the G2 Filter, Defendants knew or should have known that using the G2 Filter in its intended use or in a reasonably foreseeable manner created a significant risk of a patient suffering severe health side effects, including, but not limited to: hemorrhage; cardiac/pericardial tamponade; cardiac arrhythmia and other symptoms similar to myocardial infarction; perforations of tissue, vessels and organs; and other severe personal injuries and diseases, which are permanent in nature, including, but not limited to, death, physical pain and mental anguish, scarring and disfigurement, diminished enjoyment of life, continued medical care

and treatment due to chronic injuries/illness proximately caused by the device; and the continued risk of requiring additional medical and surgical procedures including general anesthesia, with attendant risk of life threatening complications.

142. Defendants knew or reasonably should have known that consumers or users of the Meridian Filter would not realize the danger associated with using the device in its intended use and/or in a reasonably foreseeable manner.

143. Defendants breached their duty to exercise reasonable and prudent care in the development, testing, design, manufacture, inspection, marketing, labeling, promotion, distribution and sale of the G2 Filter in, among other ways, the following acts and omissions:

a. Designing and distributing a product in which they knew or should have known that the likelihood and severity of potential harm from the product exceeded the burden of taking safety measures to reduce or avoid harm;

b. Failing to use reasonable care in manufacturing the product and producing a product that differed from their design or specifications or from other typical units from the same production line;

c. Failing to use reasonable care to warn or instruct Plaintiff, Plaintiff's physicians, or the general health care community about the G2 Filter's substantially dangerous condition or about facts making the product likely to be dangerous;

d. Failing to perform reasonable pre and post-market testing of the G2 Filter to determine whether or not the product was safe for its intended use;

e. Failing to provide adequate instructions, guidelines, and safety precautions to those persons to whom it was reasonably foreseeable would prescribe, use, and implant the G2 Filter;

f. Advertising, marketing and recommending the use of the G2 Filter, while concealing and failing to disclose or warn of the dangers known by the Defendants to be connected with and inherent in the use of the G2 Filter;

g. Representing that the G2 Filter was safe for its intended use when in fact, the Defendants knew and should have known the product was not safe for its intended purpose;

h. Continuing manufacture and sale of the G2 Filters with the knowledge that said product was dangerous and not reasonably safe, and failing to comply with FDA regulations and policy;

i. Failing to use reasonable and prudent care in the design, research, manufacture, and development of the G2 Filter so as to avoid the risk of serious harm associated with the use of the G2 Filter;

j. Advertising, marketing, promoting and selling the G2 Filter for uses other than as approved and indicated in the product's label;

k. Failing to establish an adequate quality assurance program used in the manufacturing of the G2 Filter System;

l. Failing to establish and maintain and adequate post-market surveillance program. Failing to establish and maintain and adequate post-market surveillance program.

144. A reasonable manufacturer, distributor, or seller under the same or similar circumstances would not have engaged in the before-mentioned acts and omissions.

145. As a direct and proximate result of the foregoing negligent acts and omissions by Defendants, Plaintiff has suffered and will continue to suffer serious physical injuries, economic loss, loss of enjoyment of life, disability, and other losses, in an amount to be determined at trial.

COUNT TWO: STRICT PRODUCTS LIABILITY - FAILURE TO WARN

146. Plaintiff re-alleges and incorporates by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

147. Defendants designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold the G2 Filter, including the one implanted into Plaintiff, into the stream of commerce and in the course of same, directly advertised and marketed the device to consumers or persons responsible for consumers, and therefore had a duty to warn of risk of harm associated with the use of the device and to provide adequate instructions on the safe and proper use of the device.

148. At the time Defendants designed, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold the device into the stream of commerce, Defendants knew or should have known the device was defective and presented an unreasonable danger to users of the product when put to its intended and reasonably anticipated use. The Defendants failed to adequately warn of the device's known or reasonably scientifically knowable dangerous propensities, and failed to provide adequate instructions on the safe and proper use of the device.

149. The Defendants knew or should have known at the time they manufactured, labeled, distributed and sold the G2 Filter, which was implanted in Plaintiff, that the G2 Filter, *inter alia*, posed a significant and higher risk than other similar devices of device failure (fracture, migration, tilting, and perforation of the vena cava wall) and resulting serious injuries.

150. Therefore, Defendants had a duty to warn of the risk of harm associated with the use of the device and to provide adequate instructions on the safe and proper use of the device. Defendants further had a duty to warn of dangers and proper safety instructions that it became aware of even after the device was distributed and implanted in Plaintiff.

151. The Defendants failed to timely and reasonably warn of material facts regarding the safety and efficacy of the G2 Filter. No health care provider, including Plaintiff's physicians, or patient would have used the device in the manner directed, had those facts been made known to the prescribing healthcare providers and/or ultimate users of the device.

152. The warnings, labels, and instructions provided by the Defendants at all times relevant to this action, are and were inaccurate, intentionally misleading, and misinformed and misrepresented the risks and benefits and lack of safety and efficacy associated with the device.

153. The Defendants failed to perform, establish or otherwise facilitate adequate testing and/or quality assurance programs; either of which would have shown that the device posed serious and potential life threatening adverse effects and complications.

154. The health risks associated with the device as described herein are of such a nature that ordinary consumers would not have readily recognized the potential harm. The device, which was designed, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold into the stream of commerce by the Defendants, was defective at the time of release into the stream of commerce due to inadequate warnings, labeling and/or instructions accompanying the product.

155. When Plaintiff was implanted with the device, the Defendants failed to provide any warnings, instructions, or labels regarding the severity and extent of health risks posed by the device, as discussed herein.

156. Neither Plaintiff nor his health care providers knew of the substantial danger associated with the intended and foreseeable use of the device as described herein until after Plaintiff's injury.

157. Plaintiff and Plaintiff's health care providers used the device in a normal, customary, intended, and foreseeable manner, namely as a surgically implanted device used to prevent pulmonary embolisms.

158. Upon information and belief, the G2 Filter implanted in Plaintiff was defective and unreasonably dangerous at the time of release into the stream of commerce due to inadequate warnings, labeling and/or instructions accompanying the product.

159. The G2 Filter implanted in Plaintiff was in the same condition as when it was manufactured, inspected, marketed, labeled, promoted, distributed and sold by Defendants.

160. As a direct and proximate result of Defendants' lack of sufficient warning and/or instructions, Plaintiff has suffered and will continue to suffer serious physical injuries, economic loss, loss of enjoyment of life, disability, and other losses, in an amount to be determined at trial.

COUNT THREE: STRICT PRODUCTS LIABILITY – DESIGN DEFECTS

161. Plaintiff re-alleges and incorporates by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

162. At all times relevant to this action, Defendants developed, tested, designed, manufactured, inspected, labeled, promoted, distributed and sold into the stream of commerce the G2 Filter, including the one implanted in Plaintiff.

163. The G2 Filter was expected to, and did, reach its intended consumers without substantial change in the condition in which it was in when it left Defendants' possession. In the alternative, any changes that were made to G2 Filter implanted in Plaintiff were reasonably foreseeable to Defendants.

164. The G2 Filter implanted in Plaintiff was defective in design because it failed to perform as safely as persons who ordinarily use the product would have expected at the time of use.

165. The G2 Filter implanted in Plaintiff was defective in design, in that its risks of harm exceeded its claimed benefits.

166. Plaintiff and Plaintiff's health care providers used the G2 Filter in a manner that was reasonably foreseeable to Defendants.

167. Neither Plaintiff, nor Plaintiff's health care providers could have by the exercise of reasonable care discovered the devices defective condition or perceived its unreasonable dangers prior to Plaintiff's implantation with the device.

168. As a direct and proximate result of the G2 Filter's defective design, Plaintiff has suffered and will continue to suffer serious physical injuries, economic loss, loss of enjoyment of life, disability, and other losses, in an amount to be determined at trial.

COUNT FOUR: STRICT PRODUCTS LIABILITY – MANUFACTURING DEFECT

169. Plaintiff re-alleges and incorporates by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

170. Defendants designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold the G2 Filter that was implanted into Plaintiff.

171. The G2 Filter implanted in Plaintiff contained a manufacturing defect when it left the Defendants' possession. The device differed from said Defendants' intended result and/or from other ostensibly identical units of the same product line.

172. Plaintiff and Plaintiff's health care providers used the device in a manner that was reasonably foreseeable to Defendants.

173. As a result of this condition, the product injured Plaintiff and failed to perform as safely as the ordinary consumer would expect when used in a reasonably foreseeable manner.

174. As a direct and proximate result of the G2 Filter's manufacturing defect, Plaintiff has suffered and will continue to suffer serious physical injuries, economic loss, loss of enjoyment of life, disability, and other losses, in an amount to be determined at trial.

COUNT FIVE: BREACH OF EXPRESS WARRANTY

175. Plaintiff re-alleges and incorporates by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

176. The Defendants through their officers, directors, agents, representatives, and written literature and packaging, and written and media advertisement, expressly warranted that the G2 Filter was safe and fit for use by consumers, was of merchantable quality, did not produce dangerous side effects, and was adequately tested and fit for its intended use.

177. At the time of making such express warranties, the Defendants knew and/or should have known that the G2 Filter did not conform to the express warranties and representations and that, in fact, the G2 Filter is not safe and poses serious health risks, of which the Defendants did not accurately warn.

178. As a foreseeable, direct, and proximate result of the breach of the express warranties, Plaintiff suffered severe personal injuries and economic loss.

179. Plaintiff, his health care providers, and other consumers relied on the express warranties made by the Defendants regarding the safety and efficacy of the G2 Filter and were reasonable in doing so.

180. The Defendants inclusive, and each of them, breached their express warranties because the G2 Filter was and continues to be defective and not reasonably safe for its intended purpose.

181. The Defendants expressly represented and warranted to the medical community and American consumers, including Plaintiff and his healthcare providers that the G2 Filter was safe and fit for the purposes intended, that it was of merchantable quality, that it did not pose dangerous health risks in excess of those risks associated with use of other similar devices, that the side effects it did produce were accurately reflected in the warnings, and that it was adequately tested and fit for its intended use.

182. The Defendants knew and should have known that the representations and express warranties were false, misleading, and untrue in that said Defendants knew the G2 Filter was not safe and fit for its intended use, and that the G2 Filter caused its users serious injuries that were not adequately warned of, identified, or represented by these Defendants.

183. As a foreseeable, direct and proximate result of the Defendants breaching their express warranties, as described herein, Plaintiff has suffered injuries as described herein.

COUNT SIX: BREACH OF IMPLIED WARRANTY

184. Plaintiff re-alleges and incorporates by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

185. At all times relevant to this action, the Defendants designed, researched, developed, manufactured, tested, labeled, inspected, advertised, promoted, marketed, sold, and distributed into the stream of commerce the G2 Filter for use as a temporary surgically implanted device used to prevent pulmonary embolisms and for uses other than as approved and indicated in the product's instructions, warnings, and labels.

186. At the time and place of the sale, distribution, and supply of the Defendants' G2 Filter to Plaintiff by way of his health care providers and medical facilities, the Defendants expressly represented and warranted, by labeling materials submitted with the product, that the G2 Filter was safe and effective for its intended use.

187. The Defendants knew of the intended use of the G2 Filter, at the time they marketed, sold, and distributed the product for use by Plaintiff, and impliedly warranted the product to be of merchantable quality, and safe and fit for its intended use.

188. The Defendants impliedly represented and warranted to the healthcare community, Plaintiff and his health care providers, that the G2 Filter was safe and of merchantable quality and fit for the ordinary purpose for which the product was intended and marketed to be used.

189. The representations and implied warranties made by the Defendants were false, misleading, and inaccurate because the Eclipse Filter was defective, unsafe, unreasonably dangerous, and not of merchantable quality, when used as it was marketed and intended to be used. Specifically, at the time Plaintiff purchased the G2 Filter from the Defendants, through his attending physicians and medical facilities, it was not in a merchantable condition in that:

a. It was designed in such a manner so as to be prone to a statistically high incidence of failure, including fracture, migration, excessive tilting, and perforation of the inferior vena cava; and

b. It was designed in such a manner so as to result in a statistically significant incidence of injury to the organs and anatomy.

190. Plaintiff and his health care providers reasonably relied on the superior skill and judgment of the Defendants as the designers, researchers and manufacturers of the product, as to whether the G2 Filter was of merchantable quality and safe and fit for its intended use, and also relied on the implied warranty of merchantability and fitness for the particular use and purpose for which the G2 Filter was manufactured and sold.

191. The Defendants placed the G2 Filter into the stream of commerce in a defective, unsafe, and unreasonably dangerous condition, and the product was expected to and did reach Plaintiff without substantial change in the condition in which the G2 Filter was manufactured and sold.

192. The Defendants breached their implied warranty because their G2 Filter was not fit for its intended use and purpose.

193. As a proximate result of the Defendants breaching their implied warranties, Plaintiff was caused to suffer the injuries and damages described in this complaint.

COUNT SEVEN: NEGLIGENT MISREPRESENTATION

194. Plaintiff re-alleges and incorporates by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

195. At all times relevant to this cause, and as detailed *supra*, the Defendants negligently provided Plaintiff, the public at large, and the medical community, with false or incorrect information, or omitted or failed to disclose material information concerning the G2 Filter, including, but not limited to, misrepresentations relating to the following subject areas:

a. The safety of the G2 Filter;

b. The efficacy of the G2 Filter;

c. The rate of failure of the G2 Filter; and

d. The approved uses of the G2 Filter.

196. The information distributed by the Defendants to the public, the medical community and Plaintiff was in the form of reports, press releases, advertising campaigns, labeling materials, print advertisements, commercial media containing material representations, which were false and misleading, and contained omissions and concealment of the truth about the dangers of the use of the G2 Filter. The Defendants made the foregoing misrepresentations knowing that they were false or without reasonable basis. These materials included instructions for use and warning document that was included in the package of the G2 Filter that was implanted in Plaintiff.

197. The Defendants' intent and purpose in making these misrepresentations was to deceive and defraud the public and the medical community, including Plaintiff's healthcare providers; to gain the confidence of the public and the medical community, including Plaintiff's healthcare providers; to falsely assure them of the quality of the G2 Filter and its fitness for use; and to induce the public and the medical community, including Plaintiff's healthcare providers to request, recommend, prescribe, implant, purchase, and continue to use the G2 Filter.

198. The foregoing representations and omissions by the Defendants were in fact false. The G2 Filter is not safe, fit, and effective for human use in its intended and reasonably foreseeable manner. The use of the G2 Filter is hazardous to the user's health, and said device has a serious propensity to cause users to suffer serious injuries, including without limitation, the injuries Plaintiff suffered. Further, the device has a significantly higher rate of failure and injury than do other comparable devices.

199. In reliance upon the false and negligent misrepresentations and omissions made by the Defendants, Plaintiff and his health care providers were induced to, and did use the G2 Filter, thereby causing Plaintiff to sustain severe and permanent personal injuries. The Defendants knew and had reason to know that Plaintiff, his health care providers, and the general medical community did not have the ability to determine the true facts intentionally and/or negligently concealed and misrepresented by the Defendants, and would not have prescribed and implanted same, if the true facts regarding the device had not been concealed and misrepresented by the Defendants.

200. The Defendants had sole access to material facts concerning the defective nature of the product and its propensity to cause serious and dangerous complications in the form of dangerous injuries and damages to persons who are implanted with the G2 Filter.

201. At the time the Defendants failed to disclose and misrepresented the foregoing facts, and at the time Plaintiff used the G2 Filter, Plaintiff and his health care providers were unaware of said Defendants' negligent misrepresentations and omissions.

202. Plaintiff, his health care providers and the general medical community reasonably relied upon the misrepresentations and omissions made by the Defendants where knowledge of the concealed and misrepresented facts were critical to understanding the true dangers inherent in the use of the G2 Filter.

203. Plaintiff and his health care provider's reliance on the foregoing misrepresentations and omissions by the Defendants was the direct and proximate cause of Plaintiff's harm as described herein.

COUNT EIGHT: PUNITIVE DAMAGES ALLEGATIONS

204. Plaintiff re-alleges each and every allegation in this Complaint and incorporates each allegation into this Count, as if set forth at length, in its entirety.

205. Plaintiff is entitled to an award of punitive and exemplary damages based upon Defendants' intentional, willful, knowing, fraudulent, malicious acts, omissions, and conduct, and their complete and total reckless disregard for the public safety and welfare.

206. Defendants had knowledge of, and were in possession of evidence demonstrating that, the G2 Filter was defective and unreasonably dangerous and had a substantially higher failure rate than did other similar devices on the market. Yet, Defendants failed to:

a. Inform or warn Plaintiff or his health care providers of the dangers;

b. To establish and maintain an adequate quality and post-market surveillance system; and

c. Recall the G2 Filter from the market.

207. Defendants acted to serve their own interests and having reasons to know and consciously disregarding the substantial risk that their product might kill or significantly harm patients, or significantly injure the rights of others, and consciously pursued a course of conduct knowing that such conduct created a substantial risk of significant harm to other persons.

208. As a direct, proximate, and legal result of Defendants' acts and omissions a described herein, and Plaintiff implantation with Defendants' defective product, Plaintiff has suffered and will continue to suffer serious physical injuries, economic loss, loss of enjoyment of life, disability, and other losses, in an amount to be determined at trial.

V. PRAYER FOR DAMAGES

WHEREFORE, Plaintiff, Gregory L. Moody, prays for relief on the entire complaint, as follows:

a. Judgment to be entered against all defendants on all causes of action of this Complaint, including but not limited to:

   1. Physical pain and suffering in the past and which, in reasonable probability, he will continue to suffer in the future;

   2. Physical impairment and incapacity in the past and which, in reasonable probability, he will continue to suffer in the future;

   3. Pain, suffering and mental anguish in the past and which, in reasonable probability, he will sustain in the future;

   4. Reasonable and necessary medical expenses for treatment received in the past and, based upon reasonable medical probability, the reasonable medical expenses he will need in the future;

   5. Loss of earning capacity in the past and future; and

   6. Punitive damages.

b. Plaintiff be awarded full, fair, and complete recovery for all claims and causes of action relevant to this action;

c. Plaintiff be awarded all appropriate costs, fees, expenses, and pre-

judgment and post judgment interest pursuant to the laws of the State of Tennessee as authorized by law on the judgments entered in Plaintiff's behalf; and,

d. Such other relief the court deems just and proper.

VI. DEMAND FOR JURY TRIAL

Plaintiff hereby demands trial by jury on all issues.

Dated: July 1, 2020

Respectfully Submitted,

/s/ Joey P. Leniski , Jr.
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